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Attorneys for Plaintiff Esperion Therapeutics, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC.,	)	
	)	
	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 24-_____
	)	
SANDOZ INC.,	)	
	)	
Defendant.	)	
	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendant Sandoz Inc. ("Sandoz"). This action arises out of Sandoz's submission of Abbreviated New Drug Application ("ANDA") Nos. 219347 and 219346 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NEXLETOL® and NEXLIZET® prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

3. Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

4. Upon information and belief, Sandoz is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

5. Upon information and belief, Sandoz directly or through its affiliates markets and sells drug products throughout the United States, including in the state of New Jersey.

6. Upon information and belief, Sandoz directly or through its affiliates markets and sells drug products throughout the United States, including in New Jersey.

7. Upon information and belief, Sandoz works directly or through its affiliates on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

8. Upon information and belief, Sandoz prepared and submitted ANDA No. 219347 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Sandoz NEXLETOL® ANDA Product") prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714 and 11,613,511.

9. Upon information and belief, Sandoz directly or through its affiliates developed the Sandoz NEXLETOL® ANDA Product.

10. Upon information and belief, Sandoz is seeking regulatory approval from the FDA to market and sell the Sandoz NEXLETOL® ANDA Product throughout the United States, including in New Jersey.

11. Upon information and belief, Sandoz intends to obtain approval for Sandoz's ANDA No. 219347, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Sandoz NEXLETOL® ANDA Product in the United States, including in New Jersey.

12. Upon information and belief, Sandoz prepared and submitted ANDA No. 219346 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLIZET® ("Sandoz NEXLIZET® ANDA Product") prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

13. Upon information and belief, Sandoz directly or through its affiliates developed the Sandoz NEXLIZET® ANDA Product.

14. Upon information and belief, Sandoz is seeking regulatory approval from the FDA to market and sell the Sandoz NEXLIZET® ANDA Product throughout the United States, including in New Jersey.

15. Upon information and belief, Sandoz intends to obtain approval for Sandoz's ANDA No. 219346, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Sandoz because, on information and belief, Sandoz is a corporation with its principal place of business in New Jersey and is qualified to do business in New Jersey.

18. In view of the foregoing, Sandoz is subject to general personal jurisdiction in New Jersey.

19. This Court also has personal jurisdiction over Sandoz because Sandoz, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219347 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219347, Sandoz will make, use, import, sell, and/or offer for sale the Sandoz NEXLETOL® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714 and 11,613,511.

20. This Court has personal jurisdiction over Sandoz because Sandoz, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219346 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219346, Sandoz directly or through its affiliates, will make, use, import, sell, and/or offer for sale the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,926,584, 11,760,714, 11,613,511, 10,912,751, and 11,744,816.

21. This Court also has personal jurisdiction over Sandoz because, among other things, this action arises from Sandoz's actions directed toward New Jersey, and because, upon information and belief, Sandoz has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) creating a presence in New Jersey through its registration with both the New Jersey Division of Revenue and Enterprise Services, as a business operating in New Jersey under Business Entity ID Nos. 0101056767 and 0100097265, and the New Jersey Department of Health, as a drug manufacturer and wholesaler, and maintaining a Drug and Medical Device Certificate of Registration under Registration No. 5003732. Sandoz has, therefore, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

22. In addition, this Court has personal jurisdiction over Sandoz because, among other things, upon information and belief, (1) Sandoz filed its ANDAs for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the Sandoz NEXLETOL® ANDA Product and the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey, and (2) upon approval of Sandoz's ANDAs, Sandoz will market, distribute, offer for sale, sell, and/or import the Sandoz NEXLETOL® ANDA Product and the Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of these Sandoz ANDA Products in New Jersey. Upon information and belief, upon approval of Sandoz's ANDAs, the Sandoz NEXLETOL® ANDA Product and the Sandoz NEXLIZET® ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by

physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

23. This Court also has personal jurisdiction over Sandoz because Sandoz regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing Complaints and counterclaims in this District and by being sued in this District without challenging personal jurisdiction, including in at least *Axsome Malta Ltd. v. Alkem Laboratories, Ltd.*, C.A. No. 24-cv-04608, Dkt. No. 14 (D.N.J. filed Apr. 26, 2024); *Allergan Sales, LLC v. Sandoz, Inc.*, C.A. No. 17-cv-10129, Dkt. No. 18 (D.N.J. filed Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, C.A. No. 17-cv-08825, Dkt. No. 14 (D.N.J. filed Jan. 23, 2018); and *Sandoz Inc. v. Daiichi Sankyo, Inc.*, C.A. No. 16-cv-00994, Dkt. 1, (D.N.J. filed Feb. 22, 2016).

24. Based on the foregoing systematic and continuous contacts with New Jersey, Sandoz is subject to specific personal jurisdiction in New Jersey.

25. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Sandoz to litigate this action in this Court, and Sandoz is subject to personal jurisdiction in New Jersey.

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

27. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Sandoz is a corporation with its regular and established principal place of business in New Jersey, is subject to personal jurisdiction in this Court, as set forth above, has committed acts of infringement, and, upon information and belief, will commit further acts of infringement in New Jersey.

28. Venue is also proper in this Court for Sandoz because it has a regular and established place of business in New Jersey at least because, upon information and belief, it (1) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (2) has acted to prepare and file its ANDAs, and to seek approval from the FDA to market and sell the Sandoz NEXLETOL® ANDA Product and Sandoz NEXLIZET® ANDA Product in the United States, including in New Jersey.

THE PATENTS-IN-SUIT

29. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit A."

30. Esperion is the assignee of, and holds all rights, title and interest in the '584 Patent.

31. The '584 Patent currently expires on June 19, 2040.

32. U.S. Patent No. 11,760,714 (the "'714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit B."

33. Esperion is the assignee of, and holds all rights, title and interest in the '714 Patent.

34. The '714 Patent currently expires on June 19, 2040.

35. U.S. Patent No. 11,613,511 (the "'511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit C."

36. Esperion is the assignee of, and holds all rights, title and interest in the '511 Patent.

37. The '511 Patent currently expires on June 19, 2040.

38. U.S. Patent No. 10,912,751 (the "'751 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on February 9, 2021. A true and correct copy of the '751 Patent is attached hereto as "Exhibit D."

39. Esperion is the assignee of, and holds all rights, title and interest in the '751 Patent.

40. The '751 Patent currently expires on March 14, 2036.

41. U.S. Patent No. 11,744,816 (the "'816 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on September 5, 2023. A true and correct copy of the '816 Patent is attached hereto as "Exhibit E."

42. Esperion is the assignee of, and holds all rights, title and interest in the '816 Patent.

43. The '816 Patent currently expires on March 14, 2036.

44. All claims of the '584, '714, '511, '751, and '816 Patents are valid, enforceable, and not expired.

ESPERION'S NEXLETOL® PRODUCT

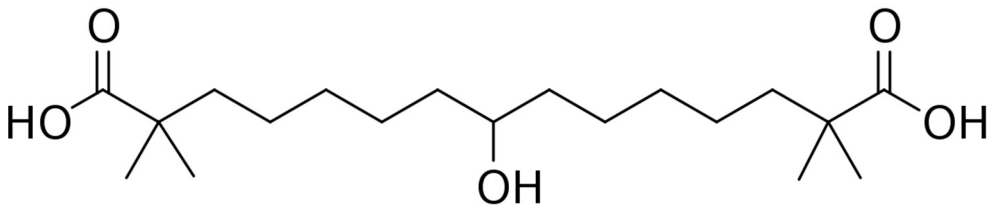
45. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL® and NEXLIZET®.

46. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

47. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in

adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD, and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

48. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



49. The claims of the ’584, ’714, and ’511 Patents cover NEXLETOL®.

50. The ’584, ’714, and ’511 Patents have been listed in connection with NEXLETOL® in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”[1]

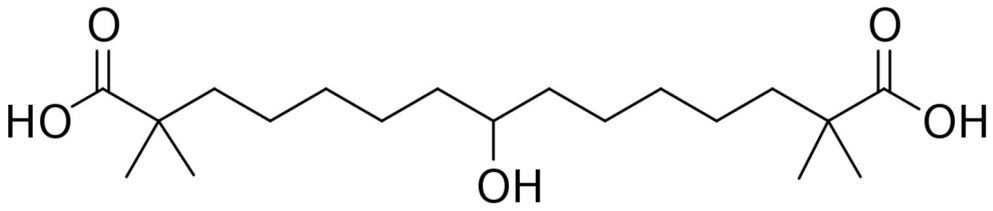
ESPERION’S NEXLIZET® PRODUCT

51. Esperion is the holder of NDA No. 211617, which was approved by the FDA on February 26, 2020, for the marketing and sale of a combined bempedoic acid and ezetimibe product in the United States under the trade name “NEXLIZET®.” Esperion sells NEXLIZET® in the United States pursuant to NDA No. 211617.

[1] The ’816 Patent has also been listed in connection with NEXLETOL® in the Orange Book, but Sandoz has not indicated in its NEXLETOL® Notice Letter (defined below) that it has submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’816 Patent.

52. NEXLIZET® is a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). The bempedoic acid component of NEXLIZET® is indicated to reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

53. Bempedoic acid, one of the active pharmaceutical ingredients in NEXLIZET®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



54. Ezetimibe, the other active pharmaceutical ingredient in NEXLIZET®, has the chemical name 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone.

55. The claims of the ’584, ’714, ’511, ’751, and ’816 Patents cover NEXLIZET®.

56. The ’584, ’714, ’511, ’751, and ’816 Patents have been listed in connection with NEXLIZET® in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the “Orange Book.”

SANDOZ'S NEXLETOL® ANDA PRODUCT

57. Upon information and belief, by letter dated April 8, 2024, and received by Esperion via Federal Express no earlier than on April 9, 2024 (the "April 8th NEXLETOL® Notice Letter"), Sandoz notified Esperion that Sandoz had submitted ANDA No. 219347 to the FDA for a generic version of NEXLETOL®.

58. Upon information and belief, in the April 8th Notice Letter, Sandoz stated that ANDA No. 219347 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Sandoz also contended that the '714 and '511 are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Sandoz NEXLETOL® ANDA Product.

59. By letter dated April 24, 2024, and received by Esperion via Federal Express no earlier than on April 25, 2024 (the "April 24th NEXLETOL® Notice Letter"), Sandoz notified Esperion that Sandoz had submitted an amended patent certification to ANDA No. 219347.

60. In the April 24th NEXLETOL® Notice Letter, Sandoz stated that it had submitted an amended certification to ANDA No. 219347 to also include a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. Sandoz also contended that the '584 Patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Sandoz NEXLETOL® ANDA Product.

61. The April 8th and April 24th NEXLETOL® Notice Letters state that Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Sandoz NEXLETOL® ANDA product before the expiration of the '584, '714 and '511 Patents. Upon information and belief, Sandoz intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Sandoz NEXLETOL® ANDA product promptly upon receiving FDA approval to do so.

62. By submitting ANDA No. 219347, Sandoz has represented to the FDA that the Sandoz NEXLETOL® ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

63. Upon information and belief, Sandoz had knowledge of at least the '714 and '511 Patents when it submitted ANDA No. 219347 to the FDA.

64. Upon information and belief, Sandoz had knowledge of the '584 Patent at least on or before April 24, 2024.

65. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product immediately and imminently upon approval of ANDA No. 219347.

66. On or before May 10, 2024, pursuant to an Offer of Confidential Access, Sandoz produced portions of its ANDA No. 219347 to Esperion. Sandoz refused to produce the entirety of ANDA No. 219347 to Esperion and refused to provide samples of its ANDA Product or components.

67. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the April 8th and April 24th NEXLETOL® Notice Letters.

SANDOZ'S NEXLIZET® ANDA PRODUCT

68. By letter dated April 24, 2024, and received by Esperion via Federal Express no earlier than on April 25, 2024 (the "NEXLIZET® Notice Letter"), Sandoz notified Esperion that Sandoz had submitted ANDA No. 219346 to the FDA for a generic version of NEXLIZET® (the Sandoz NEXLIZET® ANDA Product").

69. The NEXLIZET® Notice Letter states that Sandoz seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Sandoz NEXLIZET® ANDA product before the expiration of the '584, '714, '511, '751, and '816 Patents. Upon information and belief,

Sandoz intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Sandoz NEXLIZET® ANDA product promptly upon receiving FDA approval to do so.

70. By submitting ANDA No. 219346, Sandoz has represented to the FDA that the Sandoz NEXLIZET® ANDA Product has the same active ingredient, dosage form, and strength as NEXLIZET® and is bioequivalent to NEXLIZET®.

71. In the NEXLIZET® Notice Letter, Sandoz stated that ANDA No. 219346 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584, '714, '511, '751, and '816 Patents. Sandoz also contended that the '584, '714, '511, '751, and '816 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz NEXLIZET® ANDA Product.

72. Upon information and belief, Sandoz had knowledge of the '714, '511, '751, and '816 Patents when it submitted ANDA No. 219346 to the FDA.

73. Upon information and belief, Sandoz had knowledge of the '584 Patent at least on or before April 24, 2024.

74. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product immediately and imminently upon approval of ANDA No. 219346.

75. Sandoz's NEXLIZET® Notice Letter identified invalidity and noninfringement positions with respect to the '584, '714, '511, '751, and '816 Patents and included limited information about the Sandoz NEXLIZET® ANDA Product. Sandoz's Offer of Confidential Access permitted access only to limited, unspecified portions of Sandoz's ANDAs on terms and conditions set by Sandoz.

76. On April 29, 2024, Esperion requested Sandoz send its proposed Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219346.

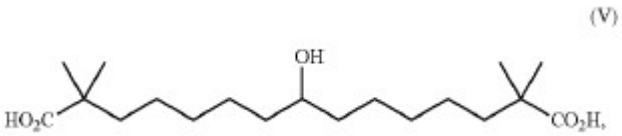
77. Sandoz has not provided Esperion with any portions of its ANDA No. 219346 and refused to provide samples of its ANDA Product or components.

78. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the NEXLIZET® Notice Letter.

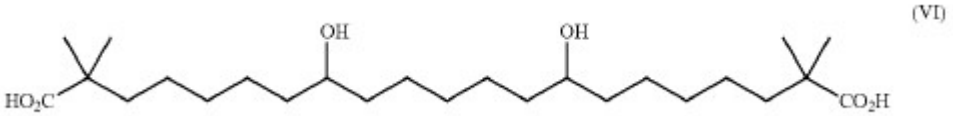
COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,926,584 BY SANDOZ'S NEXLETOL® ANDA PRODUCT

79. Esperion incorporates each of the preceding paragraphs 1 – 78 as if fully set forth herein.

80. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



81. Sandoz's submission of ANDA No. 219347 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '584 Patent constituted an act of direct and/or indirect infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

82. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product prior to expiration of the '584 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

83. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219347, Sandoz will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Sandoz NEXLETOL® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

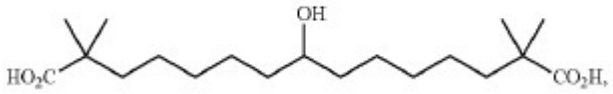
84. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219347 is approved by marketing the Sandoz NEXLETOL® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

85. Upon information and belief, Sandoz's ANDA No. 219347 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLETOL® ANDA Product.

86. Upon information and belief, upon FDA approval of ANDA No. 219347, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLETOL® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

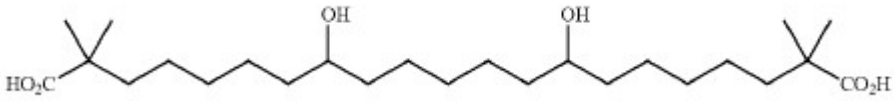
87. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

(VI)



88. Upon information and belief, the use of the Sandoz NEXLETOL® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

89. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's April 24th NEXLETOL® Notice Letter, Sandoz has knowledge of the '584 Patent and knowledge that its Sandoz NEXLETOL® ANDA Product will infringe the '584 Patent.

90. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLETOL® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

91. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219347 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Sandoz NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

92. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

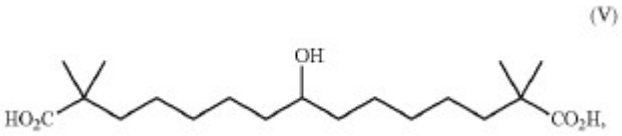
93. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

94. Unless Sandoz is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

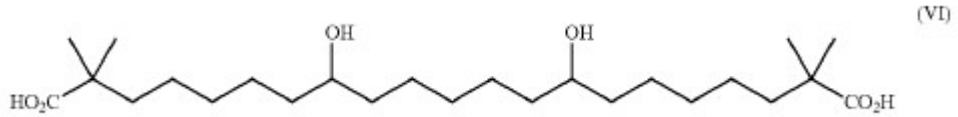
COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,926,584 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

95. Esperion incorporates each of the preceding paragraphs 1-94 as if fully set forth herein.

96. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



97. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '584 Patent constituted an act of direct and/or indirect infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

98. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '584 Patent, and Sandoz's

inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

99. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219346, Sandoz will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Sandoz NEXLIZET ® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

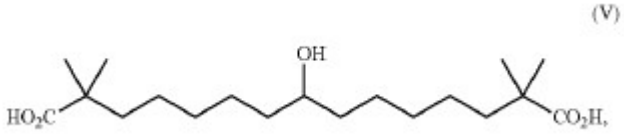
100. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET ® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

101. Upon information and belief, Sandoz's ANDA No. 219346 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLIZET ® ANDA Product.

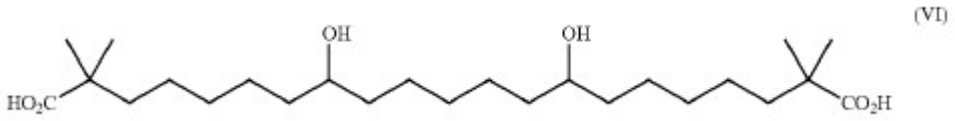
102. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET ® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

103. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising

administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



104. Upon information and belief, the use of the Sandoz NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

105. Upon information and belief, by virtue of their listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '584 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '584 Patent.

106. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLIZET® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

107. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

108. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

109. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

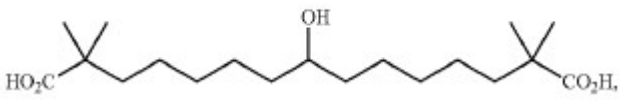
110. Unless Sandoz is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,760,714 BY SANDOZ'S NEXLETOL® ANDA PRODUCT

111. Esperion incorporates each of the preceding paragraphs 1-110 as if fully set forth herein.

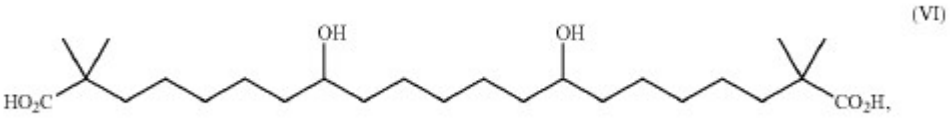
112. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than

98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

and a pharmaceutically acceptable excipient.

113. Sandoz's submission of ANDA No. 219347 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

114. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product prior to expiration of the '714 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

115. Upon information and belief, upon FDA approval of ANDA No. 219347, Sandoz intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, unless enjoined by the Court.

116. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's April 8th and April 24th NEXLETOL® Notice Letters, Sandoz has knowledge of the '714 Patent and knowledge that its Sandoz NEXLETOL® ANDA Product will infringe the '714 Patent.

117. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219347 is approved by marketing the Sandoz NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

118. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219347 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Sandoz NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

119. Sandoz's infringement is imminent because, among other things, Sandoz has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '714 Patent.

120. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

121. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

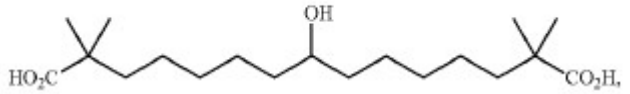
122. Unless Sandoz is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,760,714 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

123. Esperion incorporates each of the preceding paragraphs 1-122 as if fully set forth herein.

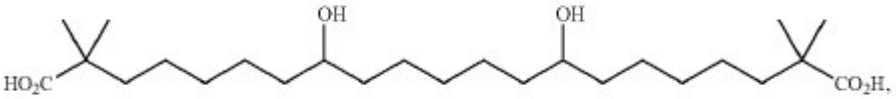
124. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

(VI)



and a pharmaceutically acceptable excipient.

125. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

126. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '714 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the

'714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

127. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court.

128. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '714 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '714 Patent.

129. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

130. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

131. Sandoz's infringement is imminent because, among other things, Sandoz has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '714 Patent.

132. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

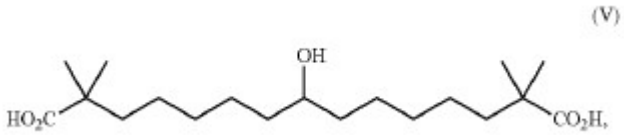
133. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

134. Unless Sandoz is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

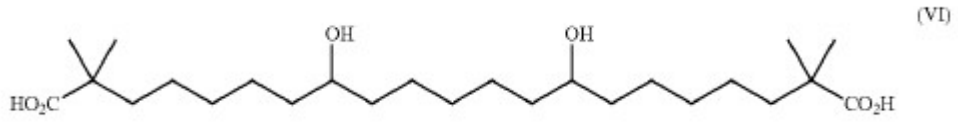
COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,613,511 BY SANDOZ'S NEXLETOL® ANDA PRODUCT

135. Esperion incorporates each of the preceding paragraphs 1-134 as if fully set forth herein.

136. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

137. Sandoz's submission of ANDA No. 219347 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

138. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLETOL® ANDA Product prior to expiration of the '511 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

139. Upon information and belief, upon FDA approval of ANDA No. 219347, Sandoz intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, unless enjoined by the Court.

140. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's April 8th and April 24th NEXLETOL® Notice Letters, Sandoz has knowledge of the '511 Patent and knowledge that its Sandoz NEXLETOL® ANDA Product will infringe the '511 Patent.

141. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA

No. 219347 is approved by marketing the Sandoz NEXLETOL® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

142. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219347 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLETOL® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Sandoz NEXLETOL® ANDA Product is not suitable for substantial noninfringing use.

143. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

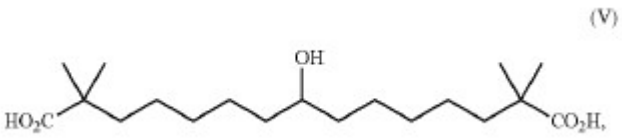
144. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLETOL® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

145. Unless Sandoz is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

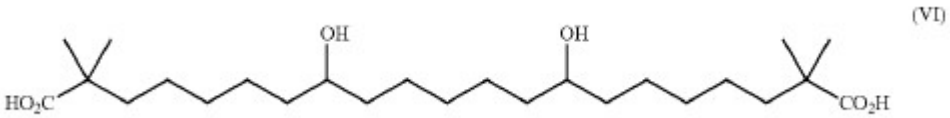
COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 11,613,511 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

146. Esperion incorporates each of the preceding paragraphs 1-145 as if fully set forth herein.

147. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

148. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

149. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '511 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

150. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court.

151. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '511 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '511 Patent.

152. Upon information and belief, Sandoz intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

153. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

154. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

155. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

156. Unless Sandoz is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT VII: INFRINGEMENT OF U.S. PATENT NO. 10,912,751 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

157. Esperion incorporates each of the preceding paragraphs 1-156 as if fully set forth herein.

158. Claim 1 of the '751 Patent claims a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

159. Sandoz's submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the '751 Patent constituted an act of infringement of the claims of the '751 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

160. Sandoz's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the '751 Patent, and Sandoz's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '751 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

161. Upon information and belief, upon FDA approval of Sandoz's ANDA No. 219346, Sandoz will infringe at least claim 1 of the '751 Patent by making, using, offering to sell, and selling the Sandoz NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '751 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

162. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging

patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '751 Patent, unless enjoined by the Court.

163. Upon information and belief, Sandoz's ANDA No. 219346 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLIZET® ANDA Product.

164. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

165. Upon information and belief, the proposed package insert will include a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

166. Upon information and belief, the use of the Sandoz NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '751 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

167. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's NEXLIZET® Notice Letter, Sandoz has knowledge of the '751 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '751 Patent.

168. On information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Sandoz NEXLIZET® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '751 Patent.

169. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '751 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

170. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '751 Patent.

171. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '751 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

172. Unless Sandoz is enjoined from directly or indirectly infringing the '751 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT VIII: INFRINGEMENT OF U.S. PATENT NO. 11,744,816 BY SANDOZ'S NEXLIZET® ANDA PRODUCT

173. Esperion incorporates each of the preceding paragraphs 1-172 as if fully set forth herein.

174. Claim 1 of the ’816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

175. Sandoz’s submission of ANDA No. 219346 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product before the expiration of the ’816 Patent constituted an act of infringement of the claims of the ’816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

176. Sandoz’s commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz NEXLIZET® ANDA Product prior to expiration of the ’816 Patent, and Sandoz’s inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the ’816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

177. Upon information and belief, upon FDA approval of Sandoz’s ANDA No. 219346, Sandoz will infringe at least claim 1 of the ’816 Patent by making, using, offering to sell, and selling the Sandoz NEXLIZET® ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the ’816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

178. Upon information and belief, Sandoz specifically intends to, and will, actively induce infringement of at least claim 1 of the ’816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219346 is approved by marketing the Sandoz NEXLIZET® ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the ’816 Patent, unless enjoined by the Court.

179. Upon information and belief, Sandoz's ANDA No. 219346 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Sandoz NEXLIZET® ANDA Product.

180. Upon information and belief, upon FDA approval of ANDA No. 219346, Sandoz intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, unless enjoined by the Court, and the Sandoz NEXLIZET® ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

181. Upon information and belief, the proposed package insert will include a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

182. Upon information and belief, the use of the Sandoz NEXLIZET® ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

183. Upon information and belief, by virtue of its listing in the Orange Book and identification in Sandoz's Nexlizet® Notice Letter, Sandoz has knowledge of the '816 Patent and knowledge that its Sandoz NEXLIZET® ANDA Product will infringe the '816 Patent.

184. Upon information and belief, Sandoz is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or

prescribe, the Sandoz NEXLIZET® ANDA Product at least according to Sandoz's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

185. Upon information and belief, Sandoz intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219346 is approved, unless enjoined by the Court, because Sandoz knows that the Sandoz NEXLIZET® ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Sandoz NEXLIZET® ANDA Product is not suitable for substantial noninfringing use.

186. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

187. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Sandoz's making, using, offering to sell, selling, and/or importing the Sandoz NEXLIZET® ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

188. Unless Sandoz is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Esperion asks that this Court grant the following relief:

189. A judgment that the claims of the '584, '714, and '511 Patents are infringed by Sandoz's submission of ANDA No. 219347 under 35 U.S.C. § 271(e)(2)(A);

190. A judgment that the claims of the '584, '714, '511, '751, and '816 Patents are infringed by Sandoz's submission of ANDA No. 219346 under 35 U.S.C. § 271(e)(2)(A);

191. A declaratory judgment that Sandoz's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Sandoz NEXLETOL®

ANDA Product prior to the expiration of the ’584, ’714, and ’511 Patents, would infringe the ’584, ’714, and ’511 Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

192. A declaratory judgment that Sandoz’s manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Sandoz NEXLIZET® ANDA Product prior to the expiration of the ’584, ’714, ’511, ’751, and ’816 Patents, would infringe the ’584, ’714, ’511, ’751, and ’816 Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

193. A judgment that the ’584, ’714, ’511, ’751, and ’816 Patents are not invalid or unenforceable;

194. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Sandoz’s ANDA No. 219347 shall not be earlier than the expiration of the ’584, ’714, and ’511 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

195. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Sandoz’s ANDA No. 219346 shall not be earlier than the expiration of the ’584, ’714, ’511, ’751, and ’816 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

196. An order permanently enjoining Sandoz, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Sandoz, from making, using, offering to sell, selling, or importing the Sandoz NEXLETOL® ANDA Product until after the ’584, ’714, and ’511 Patents’ expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

197. An order permanently enjoining Sandoz, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Sandoz, from making, using, offering to sell, selling, or importing the Sandoz NEXLIZET® ANDA Product until after the '584, '714, '511, '751, and '816 Patents expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

198. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Sandoz engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Sandoz NEXLETOL® ANDA Product prior to the expiration of the '584, '714, and '511 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

199. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Sandoz engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Sandoz NEXLIZET® ANDA Product prior to the expiration of the '584, '714, '511, '751, and '816 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

200. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

201. Such further and other relief as this Court deems proper and just.

Dated: May 23, 2024

/s/ *Liza M. Walsh*

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following actions:

- *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc., et al*., Civil Action No. 2:24-cv-05921-JXN-CLW
- *Esperion Therapeutics, Inc. v. Renata Limited., et al*., Civil Action No. 2:24-cv-06017-JXN-CLW
- *Esperion Therapeutics, Inc. v. Accord Healthcare Inc., et al.*, Civil Action No. 2:24-cv-06224-JXN-CLW
- *Esperion Therapeutics, Inc. v. Alkem Labs., et al.*, Civil Action No. 2:24-cv-06263-JXN-CLW
- *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, Civil Action No. 2:24-cv-06348
- *Esperion Therapeutics, Inc. v. MSN Pharmaceuticals Inc., et al.*, Civil Action No. 2:24-cv-06386

Dated: May 23, 2024

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: May 23, 2024

By: */s/ Liza M. Walsh*

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